

Appl. No. 10/715,559
Amendment dated: June 22, 2006
Reply to OA of: February 22, 2006

REMARKS

The rejection of claims 7, 11, 12, 13, 21, and 30 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention has been carefully considered but is most respectfully traversed in view of the amendments to the claims. In this regard, the Examiner's helpful suggestions are appreciated and the claims have been amended accordingly to obviate the outstanding rejections. Claim 1 has been amended to add the pH range as fully supported by the specification as originally filed and which includes the original claims. Claims 7, 11 and 12 have been cancelled without prejudice or disclaimer obviating this aspect of the rejection. Claim 13 has been corrected and claims 21 and 30 amended to obviate this aspect of the rejection. In view of the amendments to the claims, it is most respectfully requested that this rejection be withdrawn.

The rejection of claims 1, 3-5, 7, and 10-12 under 35 U.S.C. 102(b) as anticipated by Dieu et al (US 4,897,277), has been carefully considered but is most respectfully traversed.

Applicants wish to direct the Examiner's attention to MPEP § 2131 which states that to anticipate a claim, the reference must teach every element of the claim.

"A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). "The identical invention must be shown in as complete detail as is contained in the ... claim." *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236, 9 USPQ2d 1913, 1920 (Fed Cir. 1989). The elements must be arranged as required by the claim, but this is not an *ipsissimis verbis* test, i.e., identity of terminology is not required. *In re Bond*, 910 F.2d 831, 15 USPQ2d 1566 (Fed.Cir. 1990).

The rejected claims under 35 U.S.C. 102(b) as being anticipated by using a ceramic filter to remove casein under the flow pressure of 10-20 psi and at the inherent pH value of milk is noted. According to the amended claim 1, the claims have been

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limited in that the process is characterized in that the milk is subject to adjust pH value at 5.0-6.5 prior to the filtration. Namely, it is most respectfully submitted one cannot remove the casein in the milk only at its inherent pH value between 6.6-6.8 without this step. The main objective of Dieu(US 4897277) is to teach a method for producing cheese by means of microfiltration, however, Dieu did not disclose the specific pH value when removed the casein. As mentioned above, the specific pH value is the key point to remove the casein from the milk. Therefore, the amended claims 1, 3-5 and original claim 10 (claim 7, 11, 12 cancelled) are not anticipated by the method of filtering the milk using a ceramic filter and therefore it is most respectfully requested that this rejection be withdrawn.

The rejection of claims 8 and 9 under 35 U.S.C. 103(a), as being unpatentable over Dieu as applied to claim 1 above, and further in view of Holm et al (US 4,876,100) has been carefully considered but is most respectfully traversed.

Applicants wish to direct the Examiner's attention to the basic requirements of a prima facie case of obviousness as set forth in the MPEP § 2143. This section states that to establish a prima facie case of obviousness, three basic criteria first must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine the reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations.

The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, not in applicant's disclosure. In re Vaeck, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991).

Section 2143.03 states that all claim limitations must be taught or suggested by the prior art. In re Royka, 490 F.2d 981, 180 USPQ 580 (CCPA 1974). "All words in a claim must be considered in judging the patentability of that claim against the prior art." In re Wilson, 424 F.2d 1382, 1385, 165 USPQ 494, 496 (CCPA 1970). If an independent

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claim is nonobvious under 35 U.S.C. 103, then any claim depending therefrom is nonobvious. In re Fine, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988).

Applicants also most respectfully direct the Examiner's attention to MPEP § 2144.08 (page 2100-114) wherein it is stated that Office personnel should consider all rebuttal argument and evidence presented by applicant and the citation of In re Soni for error in not considering evidence presented in the specification.

Applicants most respectfully submit that Dieu (US 4,897,277) teaches that milk is subjected to a process of rennin or lactin ferments prior to thermal treatment (column 3, line 44), casein and the other proteins in the milk form a big-molecule coagulum. Dieu and Holm (US 4,876,100) teach a simple method separating the coagulum of casein from other proteins in the milk with low-rate centrifugal process (column 2, line 38) that is similar to separate the solid from water solution. However, the present invention provides a method for removing casein micelle from milk, which is the colloid solution, under a specific pH value of 5.0-6.5 and the flow pressure of 10-20psi. There is no teaching in the prior art which suggest this aspect of the invention. Applicants specification may not be used to proved the necessary motivation to modify the prior art. Accordingly, it would be non-obvious to one of ordinary skill in the art at the time of invention and it is most respectfully requested that this rejection be withdrawn.

The rejection of claim 6 under 35 U.S.C. 103(a), as being unpatentable over Dieu as applied to claim 1 above, and further in view of Mahmoud et al (US 6,051,268) has been carefully considered but is most respectfully traversed.

Mahmoud (US 6,051,268) teaches only to separate one component of interest from others at a batch, (see Mahmoud column 2, line 17-19). In the presently claimed invention, the claims use two layers of filtering membranes of diameters 0.14 μ m and 0.20 μ m to separate casein micelles from the human coagulation factor IX due to that the human coagulation factor IX only can pass through the ceramic filtering membrane. Moreover, Mahmoud does not teach to use a non-electric-charged filtering membrane to separate casein from milk, characterized in avoiding that the membranes adsorb the components of interest thus causing the excellent separation of casein from milk.

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Mahmoud only disclosed a traditional filtering process for separation the solid phase and liquid phase in the milk. As the result, the present invention disclosed a novel and unobvious method to obtain large amount of the human coagulation factor IX from the milk. Accordingly, the present invention would be non-obvious to one of ordinary skill in the art at the time of invention and this rejection should be withdrawn.

The rejection of claims 1, 3-5 and 7-12 under 35 U.S.C. 103(a), as being unpatentable over Denman et al (US 5,756,687) has been carefully considered but is most respectfully traversed.

The Denman (5,756,687) reference teaches only the separation of one component of interest from others at a batch, Denman, see column 1. In the presently claimed invention, the claims use two layers of filtering membranes of diameters 0.14 μ m and 0.20 μ m to separate casein micelles from the human coagulation factor IX due to that the human coagulation factor IX only can pass through the ceramic filtering membrane. Moreover, Denman does not teach to use a non-electric-charged filtering membrane to separate casein from milk, characterized in avoiding that the membranes adsorb the components of interest thus causing the excellent separation of casein from milk. Denman only disclosed a traditional filtering process for separation the solid phase and liquid phase in the milk. As the result, the present invention disclosed a novel method to obtain large amount of the human coagulation factor IX from the milk. Accordingly, the present invention would be non-obvious to one of ordinary skill in the art at the time of invention and the rejection should be withdrawn.

The rejection of claims 13-16, 22-28 and 29 under 35 U.S.C. 103(a), as being unpatentable over Denman et al (US 5,756,687) in view of Mahmoud et al (US 6,051,268) has been carefully considered but is most respectfully traversed.

As previously noted, the Denman (5,756,687) reference teaches only the separation of one component of interest from others at a batch (Denman: column 1). In the presently claimed invention, the claims use two layers of filtering membranes of diameters 0.14 μ m and 0.20 μ m to separate casein micelles from the human coagulation factor IX due to that the human coagulation factor IX only can pass through the ceramic

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filtering membrane. Moreover, Denman does not teach to use a non-electric-charged filtering membrane to separate casein from milk, characterized in avoiding that the membranes adsorb the components of interest thus causing the excellent separation of casein from milk. Denman only disclosed a traditional filtering process for separation the solid phase and liquid phase in the milk. As the result, the present invention disclosed a novel method to obtain large amount of the human coagulation factor IX from the milk. The deficiencies in the teachings of the primary reference are not overcome by the teachings of the secondary teaching. Moreover, applicants specification may not be used as a teaching reference.

Mahmoud teaches only to separate one component of interest from others at a batch,(see Mahmoud column 2, line 17-19). In the presently claimed invention, the claims use two layers of filtering membranes of diameters 0.14 μ m and 0.20 μ m to separate casein micelles from the human coagulation factor IX due to that the human coagulation factor IX only can pass through the ceramic filtering membrane. Moreover, Mahmoud does not teach to use a non-electric-charged filtering membrane to separate casein from milk, characterized in avoiding that the membranes adsorb the components of interest thus causing the excellent separation of casein from milk. Mahmoud only disclosed a traditional filtering process for separation the solid phase and liquid phase in the milk and the combined teachings do not render the claimed invention obvious. As the result, the present invention disclosed a novel and unobvious method to obtain large amount of the human coagulation factor IX from the milk. Accordingly, the present invention would be non-obvious to one of ordinary skill in the art at the time of invention and this rejection should be withdrawn.

The rejection of claims 17-19 under 35 U.S.C. 103(a), as being unpatentable over Denman et al (US 5,756,687) in view of Mahmoud et al (US 6,051,268) as applied to claim 13 above and further in view of Dieu has been carefully considered but is most respectfully traversed for the above reasons as discussed, and the amendments to the claims. Accordingly, it is most respectfully requested that this rejection be withdrawn.

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The rejection of claims 20-21 and 30-32 under 35 U.S.C. 103(a), as being unpatentable over Denman et al (US 5,756,687) in view of Mahmoud et al (US 6,051,268) as applied to claim 13 above in paragraph 5 and Roesink et al (US 4,798,847) has been carefully considered but is most respectfully traversed.

Roesink(US 4798,847) teaches a method comprising a process for the preparation of hydrophilic membranes by coagulation of a solution of a hydrophobic polymer and a hydrophilic polymer which suitable as microfiltration and /or ultrafiltration membranes having a symmetrical pore structure in the cross-section(see column 1, line 28-37, column 2, lines 2-4). However, the present invention aims to provide a method passing through a non-electric-charged filtering membrane to separate casein from milk, characterized in avoiding that the membranes adsorb the components of interest thus causing the excellent separation of casein from milk and the claims are not rendered obvious in view of this combination of references. Accordingly, it is most respectfully requested that this rejection be withdrawn.

In view of the above comments and further amendments to the claims favorable reconsideration and allowance of all of the claims now present in the application are most respectfully requested.

Respectfully submitted,

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